

b.) Remarks

Claims 1-7, 9-11, 13-15, 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being obvious variations of claims 1-14 of U.S. Patent No. 6,432,534. This rejection is not at all well-understood; none of the '534 patent claims recite or suggest materials which are denaturalized^{1/}, inactivated^{2/}, decomposed^{3/} or exhibit delayed elution^{4/} when pressed at 1 ton/cm² or more. Nor, for that matter, do the pending claims recite that the tablet has lubricant within the material to be molded (compare, e.g., claim 2, lines 5-7 of the '534 patent with pending claim 1, lines 10-11^{5/}).

Claim 1 is objected to as informal for the reasons noted. However, the "error" noted by the Examiner is not present; the comma was actually removed in the previous amendment. In this regard, Applicants nonetheless gratefully acknowledge the Examiner's detailed review of their claims for such inadvertent errors. The Examiner's example has led the undersigned to do the same; claims 1-4, 10, 11 and 14 are, accordingly, amended to address all such typographical or idiomatic errors noted.

^{1/} C.f., claims 1, 2, 3, 10 or 11.

^{2/} C.f., claims 1, 3 or 10.

^{3/} C.f., claims 2 or 11.

^{4/} C.f., claim 4.

^{5/} See also, claim 2 at lines 12-13, claim 3 at lines 10-11, claim 4 at lines 12-13, claim 10 at lines 6-7 and claim 11 at lines 8-9.

Claims 1-7, 9-11, 13-15, 18 and 19 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner is understood to object to the term “pulsating vibration air”. In response, Applicants respectfully wish to point out that such is a term of regular use in this art. See, for example at least U.S. Patent Nos. 5,700,492, 6,302,573 6,062,826, 6,607,008, 5,996,902 and 6,464,737 in addition to the cited U.S. Patent No. 6,432,534 noted above.

Nonetheless, solely in order to reduce the issues and for even better usage and clarity, claim 1, for instance, has been amended to change “spraying a lubricant mixed with said pulsating vibration air in said spraying chamber” to --spraying, within said spraying chamber, a lubricant admixed with said pulsating vibration air--. The other claims are amended similarly. Accordingly, this rejection too should be overcome.

Claims 10, 11 and 19 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,126,145 to Evenstad. Also, claims 10, 11, 13, 14, 18 and 19 are rejected under 35 U.S.C. §103(a) as being obvious over Evenstad. These are the sole remaining issues. Accordingly, initially, Applicants gratefully acknowledge the indication that claims 1-7, 9 and 15 recite subject matter which is patentable and unobvious over the cited art.

As to claims 10-11, 13-14 and 18-19, the rejection is respectfully traversed. However, prior to setting forth their bases for traversal, Applicants would first like to discuss the salient features of the present invention and, *inter alia*, its patentable nature over the prior art.

As the Examiner is aware, claims 10 and 11 relate to tabletted pharmaceutical compositions, e.g., containing an active agent. Claim 10 specifies that the tablet contains a tableting lubricant “only on surfaces thereof and not within” the tablet (emphasis added).

It is well-understood that “lubricants” are additives used to improve flow characteristics. Lubricants can function internally or externally. Internal lubricants, as utilized by Evenstad, reduce melt viscosity and promote flow. In contrast, the present invention utilizes external lubricants, which reduce friction between the molding material and the surfaces of the punch and die. Optimally, balancing internal and external lubrication leads to increased production rates and/or reduced energy.^{6/}

Evenstad utilizes two tabletization processes: “standard rotary” pressing (col. 7, lines 1-2) and “fluid bed” processing (col. 7, lines 21-22). In “standard rotary” pressing, all materials, including all lubricants, are mixed to produce a uniformly blended product (column 6, lines 31-68). The homogeneous admixture is then pressed.

Similarly, in fluid bed processing, all materials, including all lubricants, are also mixed to produce a uniformly blended product (column 7, lines 21-50). The homogeneous admixture is then tabletted.

In other words, Evenstad teaches conventional wet granulation and fluid bed granulation processes wherein an active component is granulated, the granulated material is

^{6/} It is important to keep in mind too that in injection moulding, external lubricants are (somewhat confusingly) referred to as internal mold release additives. (See generally, <http://www.oleofine.com/appdef.html>)

dried, the “external” lubricant is uniformly mixed with the dried granulated material, and the mixture is tableted.

In column 5, lines 39-49, Evenstad teaches:

A uniform blend of the hydrophobic component (flakes or powder) and dye, if used, is formed. The binding agent is dissolved in water to form a binding agent solution. The hydrophobic component blend, the sustaining hydroxypropyl methylcellulose, and the medicament are granulated using the binding agent solution to a final moisture level of less than about 7 percent, preferably less than about 5 percent. In the conventional process, the granulation is removed from the mixer and oven dried. External lubricating agents are then mixed in and the mixture is tableted.

From column 6, line 64 to column 7, line 2, Evenstad similarly teaches:

These batches were weighed, and combined in a ribbon blender. 3.0 kilograms glycerol behenate and 3.0 kilograms magnesium stearate were then added to the ribbon blender and the mixture was mixed for 5 minutes. The resulting product was tableted using a standard rotary press into tablets of 750 milligrams niacin.

In either event, if any “external lubricant” (e.g., a lubricant intended to promote release from the processing equipment) is utilized, it is “added to the dried granules before processing” (column 5, lines 19-20). That means the materials including the external lubricant are uniformly blended and then tableted. Accordingly, Evenstad does not teach or suggest any of

- adding an external lubricant to die or punch surfaces;
- producing a homogeneous molding material without the internal lubricant; or
- pelletizing a molding material that contains substantially no internal lubricant.

In contrast, the "external lubricant" taught by Evenstad is (as is conventional in this art) incorporated internally - it is called "external" only because it attenuates processing friction.

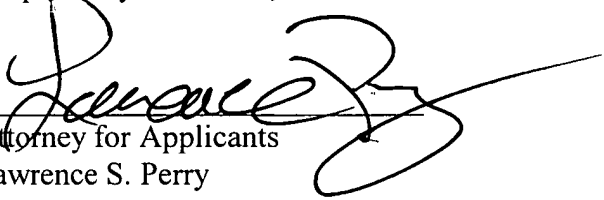
Accordingly, it should now be clearly established on the record that the teachings of Evenstad are anathema to the subject matter of the present invention.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-7, 9-11, 13-15, 18 and 19 remain presented for continued prosecution, claims 1-7, 9 and 15 having been indicated as being free of the prior art.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

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